Zogenix Provides Corporate Update and Reports First Quarter 2019 Financial Results

May 8, 2019

- ***Type A meeting with U.S. FDA expected by early June to discuss FINTEPLA® Dravet syndrome NDA expected by early June***

- ***FINTEPLA Dravet syndrome MAA accepted for review by EMA***

- ***Exclusive distribution agreement for FINTEPLA in Japan signed with Nippon Shinyaku***

EMERYVILLE, Calif., May 08, 2019 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ: ZGNX), a global pharmaceutical company developing rare disease therapies, today announced financial results for the three months ended March 31, 2019 and provided a corporate update. The Company will host a conference call today, Wednesday, May 8, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

“In the U.S., our priority remains working with the U.S. Food & Drug Administration (FDA) to address the issues identified in the Refusal to File letter (RTF) we received in April regarding our New Drug Application (NDA) for FINTEPLA® for the treatment of seizures associated with Dravet syndrome,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We recently submitted a briefing book to the Agency and requested a Type A meeting with them, which we expect will take place by early June. We remain confident in FINTEPLA’s clinical profile demonstrated in the successfully completed Phase 3 program and remain fully committed to advancing FINTEPLA as a potential new treatment option for Dravet syndrome patients and their families.”

“Our Marketing Authorization Application (MAA) for FINTEPLA in Dravet syndrome submitted to European Medicines Agency (EMA) has been under review since its acceptance in March,” continued Dr. Farr. “Also in March, we were very pleased to enter into an exclusive agreement for the commercialization of FINTEPLA in Japan with Nippon Shinyaku, whose expertise and commitment to rare diseases make the company an attractive partner there.”

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome
  • MAA accepted for review by the EMA.
  • RTF letter received from the U.S. FDA regarding the submitted NDA for FINTEPLA for the treatment of seizures associated with Dravet syndrome.
  • FDA Type A meeting expected to take place by early June to gain clarity on NDA resubmission.
  • The FDA has not requested or recommended additional clinical efficacy or safety studies of FINTEPLA.
- FINTEPLA for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS)
  • Advanced enrollment in ongoing global Phase 3 clinical trial (Study 1601) of FINTEPLA for the treatment of seizures associated with LGS; full enrollment expected in second half of 2019.
  • Top-line LGS study results anticipated in Q1 2020.
- FINTEPLA in Japan
  • Entered into an exclusive distribution agreement with Nippon Shinyaku, Co., Ltd. for the commercialization of FINTEPLA in Japan.
  • Zogenix retains responsibility for completing its global clinical development programs for FINTEPLA, including those already underway to support the Company’s planned submissions of new drug applications in Japan for Dravet syndrome and LGS.
  • Zogenix to receive $20 million upon signing and over the next two years, and will also be eligible to receive future regulatory and sales-based milestone payments worth up to $108.5 million.
  • Zogenix to supply product to Nippon Shinyaku and receive a tiered transfer price of up to a high-double digit percentage of the annual net sales of FINTEPLA in Japan.

First Quarter 2019 Financial Results

- Research and development expenses for the first quarter ended March 31, 2019, totaled $24.4 million, up from $23.0 million in the first quarter ended March 31, 2018, as the Company concluded Phase 3 clinical trials in Dravet syndrome and expanded clinical trial activities related to its ongoing Phase 3 development program of FINTEPLA in LGS.

- Selling, general and administrative expenses for the first quarter ended March 31, 2019, totaled $10.9 million, compared with $8.1 million in the first quarter ended March 31, 2018.

- Net loss for the first quarter ended March 31, 2019, was $35.2 million, or a net loss of $0.83 per share, compared with a

net loss of $30.2 million, or a net loss of $0.87 per share, in the first quarter ended March 31, 2018.

- As of March 31, 2019, the Company had $480.7 million in cash, cash equivalents, and marketable securities, compared to $514.2 million at December 31, 2018.

Conference Call

Wednesday, May 8, at 4:30 PM Eastern Time/1:30 PM Pacific Time

Toll Free (US):	877-407-9716
International:	201-493-6779
Conference ID:	13689677
Webcast:	http://public.viavid.com/index.php?id=134029

About Zogenix

Zogenix is a global pharmaceutical company committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. The company's lead candidate, FINTEPLA® (ZX008, fenfluramine) has been accepted for review by the European Medicines Agency and is in development in Japan. Zogenix is preparing for a Type A meeting with the U.S. Food & Drug Administration to discuss resubmission of the company's NDA. For more information, visit www.zogenix.com.

Forward Looking Statement

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed," and similar expressions are intended to identify forward-looking statements. These statements include the potential timing of a Type A meeting with FDA; the potential timing of acceptance and approval, if any, by the FDA of the NDA and approval, if any, by the EMA of the MAA; Zogenix's plans regarding the development of FINTEPLA in Lennox-Gastaut syndrome; Zogenix's expectations that Nippon Shinyaku will launch and commercialize FINTEPLA in Japan, if approved; the potential for FINTEPLA to address unmet medical need; and the patient population. These statements are based on Zogenix's current beliefs and expectations. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: the FDA may refuse to accept the NDA following our planned resubmission, and the FDA may disagree that the existing safety and efficacy data is sufficient to allow an NDA review and approval, the FDA may not agree with Zogenix's interpretation of the results of the clinical trials of FINTEPLA; additional data from Zogenix's ongoing studies may contradict or undermine the data submitted in the NDA for FINTEPLA; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; and other risks described in Zogenix's prior press releases as well as in public periodic filings with the U.S. Securities & Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

CONTACTS:

Zogenix
Melinda Baker
Senior Director, Corporate Communications
corpcomms@zogenix.com

Media
Rachel Lipsitz
Public Relations, Syneos Health
+1 (858) 449 9575 | rachel.lipsitz@syneoshealth.com

Investors
Andrew McDonald
Founding Partner, LifeSci Advisors LLC
+1 (646) 597-6987 | Andrew@lifesciadvisors.com

Zogenix, Inc.
Condensed Consolidated Balance Sheets (Unaudited)

(in thousands)

	March 31, 2019	December 31, 2018
Assets:		
Current assets:		
Cash and cash equivalents	$ 58,288	$ 68,454
Marketable securities	422,407	445,733
Accounts receivable	15,500	—
Prepaid expenses	8,071	6,718
Other current assets	6,323	11,825
Total current assets	510,589	532,730
Property and equipment, net	10,632	2,870
Operating lease right-of-use assets	8,423	—
Intangible assets	102,500	102,500
Goodwill	6,234	6,234
Other assets	2,154	3,997
Total assets	$ 640,532	$ 648,331
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	8,167	7,989
Accrued and other current liabilities	18,594	18,086
Deferred revenue, current	5,000	—
Current portion of operating lease liabilities	1,412	—
Current portion of contingent consideration	22,800	32,300
Total current liabilities	55,973	58,375
Deferred revenue, noncurrent	10,500	—
Operating lease liabilities, net of current portion	11,355	—
Contingent consideration, net of current portion	48,400	45,900
Deferred income taxes	17,425	17,425
Other long-term liabilities	—	3,830
Total liabilities	143,653	125,530
Commitments and contingencies		
Stockholders' equity:		
Common stock	42	42
Additional paid-in capital	1,227,620	1,218,710
Accumulated deficit	(731,156)	(695,954)
Accumulated other comprehensive income	373	3
Total stockholders' equity	496,879	522,801
Total liabilities and stockholders' equity	$ 640,532	$ 648,331

Zogenix, Inc.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 24,352	$ 22,980
Selling, general and administrative	10,918	8,070
Change in fair value of contingent consideration	3,000	—
Total operating expenses	38,270	31,050

Loss from operations	(38,270)	(31,050)
Other income (expense):		
Interest income	3,156	833
Other (expense) income, net	(88)	37
Total other income	3,068	870
Net loss	(35,202)	(30,180)
Net loss per share, basic and diluted	$ (0.83)	$ (0.87)
Weighted average common shares used in the calculation of basic and diluted net loss per common share	42,236	34,841

Source: Zogenix, Inc.